UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

JOHN DOE, by and through Jane Doe, his parent and natural guardian, on behalf of himself and all others similarly situated, Plaintiff, **v.** **PURDUE PHARMA L.P.**; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; JANSSEN PHARMACEUTICA INC and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; NORAMCO, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC., AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and MCKESSON CORPORATION; Defendants.	**CIVIL ACTION** **NO.** **COMPLAINT - CLASS ACTION** **Jury Trial Demanded**

CLASS ACTION COMPLAINT

I. INTRODUCTION

1. This petition, which requests class certification and the award of injunctive relief, presents the Court with a profound and unique opportunity to protect and improve the lives of Pennsylvania's infants and children who, through no fault of their own,[1] were diagnosed at birth with opioid-related Neonatal Abstinence Syndrome (NAS).[2] In addition to requesting the abatement of a public nuisance, the class members seek relief for ongoing medical testing, monitoring, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for symptomatic children who have been previously diagnosed with opioid-related NAS.

2. In March, 2018 the Pennsylvania Health Care Cost Containment Council reported that there during the 2016-17 fiscal year, there were over 1,900

[1] By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al. Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States. Am J Public Health. 2014 Feb; 104(2):52-9.

Similarly, the number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population. Califf RM, et al. A Proactive Response to Prescription Opioid Abuse. N Engl J Med. 2016 Apr 14; 374(15):1480-5.

[2] By 2015, the number of infants diagnosed with NAS in California was 1,190, up more than 50% from a decade earlier. Approximately one in every 400 births in California involves an NAS diagnosis. Reese, Phillip, "More California Babies Born Addicted to Drugs," Sacramento Bee, Aug. 14, 2015.

NAS is a medical and diagnostic term. The same condition has also been infrequently referred to as Neonatal Opioid Withdrawal Syndrome (NOWS) by governmental entities, including the DEA.

Pennsylvania infants born suffering from NAS, which is more than a 1,000% increase since 2000-2001.[3]

II. PARTIES

A. Plaintiff and the Putative Class

3. Neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of a child's adolescent development. These needs absolutely exist, regardless of the dosage any one child received prenatally or how he or she was weaned from these substances. These needs relate primarily to the well-known adverse effect of opioids on behavioral and regulatory development in exposed children. Every single child diagnosed with opioid-related NAS must have robust medical testing, monitoring, intervention, provision of caregiver training and information, and medical referral in order to maximize his or her future as an adult. This relief will also largely abate the public nuisance created by Defendants' conduct. For this reason Plaintiff and the class seek injunctive relief.

4. Minor Plaintiff John Doe[4] ("John" or "Plaintiff"), who resides in this District,d was diagnosed with opioid-related NAS at birth in 2015. As evidenced by

[3] Pennsylvania Healthcare Cost Containment Council Research Brief, *Hospitalizations for Newborns with Neonatal Abstinence Syndrome* (March, 2018). Created by the Pennsylvania General Assembly in 1986, the Pennsylvania Health Care Cost Containment Council ("PHC4") is an independent state agency charged with collecting, analyzing and reporting information that can be used to improve the quality and restrain the cost of health care in Pennsylvania.

[4] Counsel will seek appropriate court-ordered measures to protect John's identity and address, while also allowing the class certification process to proceed.

this diagnosis, John was exposed *in utero* to opioids by a birth mother who became addicted to opioids in 2010 after receiving a medical prescription for an opioid after a leg and ankle injury. John's caregiver and legal next friend is his mother who has cared for him since birth and has legal custody of him.

5. John and the other infants and children who make up this class have all been diagnosed with a symptomatic syndrome of disease, have a birth mother who received a medical prescription for opiates, and all now desperately require follow-up testing, monitoring, intervention, training for their caregivers (who include grandparents, foster parents, biological parents, adoptive parents, and legal guardians), and referrals for medical, psychological, and behavioral treatment. Furthermore, the necessary care plans and monitoring for these infants and children are uniform[5] because they share the same goal: maximizing the development of each exposed child.

6. John and the class members were all harmed by Defendants' wrongful conduct, and such harm was a direct and foreseeable result of that wrongful conduct.

7. Defendants are Manufacturers and Distributors of highly addictive and highly profitable prescription opioids. These FDA Class II Controlled Substances cannot find their way to a Pennsylvania woman of child-bearing years without first

[5] As will be shown in the class plan, which will be supplied to the Court in connection with class certification, robust care is medically necessary for all children.

being issued pursuant to a medical prescription.[6] Defendants' profits are theoretically limited by the amount of medically necessary opioids that can be sold through the controlled channels.

8. However, in an effort to end-run these stringent controls so that they could maximize profits, the Manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their shared legal duty both to investigate and to notify authorities of all suspected diversions of these highly dangerous substances.

9. Instead, beginning in the mid-1990s, the Manufacturer and Distributor Defendants acted in concert to create two new markets for prescription opiates which had not otherwise existed: (i) an incredibly high-volume primary market in which medical prescriptions of opioids for widespread and chronic pain[7,8] were written for

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[6] Class II controlled substances enter the market from a "closed system" of manufacturing and distribution.

[7] Of equal importance was the Manufacturer Defendants' promotion of opiate treatment without dosage ceilings. Thus, not only were they able to expand the demand to treatment of wide-spread and chronic conditions beyond cancer, but, once prescribed, the dosage of any one patient could be limitless.

Upon information and belief, not only was this done to flood the market (and increase profits), but it also served the purpose of disguising the true facts of the secondary market from the DEA and law enforcement.

[8] Prescriptions of Perdue's *OxyContin* for non-cancer related pain surged from approximately 600,000 in 1997 to 6.2 million in only 5 years. Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-7.

Pennsylvanians, including women of child-bearing age and (ii) a secondary market into which those opioids were easily diverted from the flooded primary market. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market. Soon the demand from the secondary market was further driving prescriptions written for the primary market. However, in order to maintain the highly profitable and ever-growing secondary market, the Distributor Defendants also had to conceal from the public and all governmental authorities the true facts relating to the supply of opiates flooding the primary market. Without the silence and concealment of the Distributor Defendants, the dual market scheme (and record profits) could not have existed.

10. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The net result of this behavior was to flood Pennsylvania with highly addictive, dangerous opioids, whether through the primary prescription market (including to Pennsylvania females of child-bearing age) and the secondary market. At all times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders. But for the dereliction of this legal

duty, the robust secondary market for opioids could not have existed in Pennsylvania.

B. The Manufacturer Defendants

1. The Purdue Defendants

11. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

12. Purdue manufactures the opioids OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin constitutes roughly 30% of the entire U.S. market for painkillers and is Purdue's best-selling product. Within five years of the drug's debut, it was racking up unprecedented sales of almost $3 billion dollars.

13. At all times relevant to this controversy, Purdue sold and distributed substantial amounts of opioids in Pennsylvania.

2. The Allergan/Actavis Defendants

14. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to

ALLERGAN PLC in January 2013. Prior to that (October 2012), WATSON PHARMACEUTICALS, INC. had acquired ACTAVIS, INC., and the combined company changed its name to Actavis, Inc. as of January 2013 and then to ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is either a predecessor to or else now owned by ALLERGAN PLC, which previously used or now uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products which ultimately inure to its benefit.

15. Actavis/Allergan manufacturers the branded opioid drugs Kadian (acquired from King Pharmaceuticals in 2008) and Norco (a generic version of Kadian), as well as generic versions of Duragesic and Opana in the United States. At all times relevant to this controversy, Actavis/Allergan sold and distributed substantial amounts of opioids in Pennsylvania.

3. The Cephalon/Teva Defendants

16. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petach TiNva, Israel. In 2011, Teva Ltd. Acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. These Defendants are collectively referred to as the "Cephalon" Defendants. The Cephalon Defendants collectively market and sell Cephalon products, including the opioids Actiq and Fentora in the U.S. At all times relevant to this controversy, Cephalon/Teva sold and distributed substantial amounts of opioids in Pennsylvania.

4. The Endo Defendants

17. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo." Endo develops, markets, and sells the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone,

hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

18. At all times relevant to this controversy, Endo sold and distributed substantial amounts of opioids in Pennsylvania.

5. The Janssen Defendants

19. JANSSEN PHARMACEUTICALS, INC. (f/k/a JANSSEN PHARMACEUTICA INC.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of J&J until July of 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are collectively referred to as "Janssen."[9]

[9] J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and communicates with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

20. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic. Janssen also developed, marketed, and sold (until January 2015) the opioids Nucynta and Nucynta ER. At all times relevant to this controversy, Janssen sold and distributed substantial amounts of opioids in Pennsylvania.

6. The Mallinckrodt Defendants

21. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt."

22. Mallinckrodt manufactures, markets, and sells opioids in the United States, including generic oxycodone, of which it is one of the largest manufacturers. At all times relevant to this controversy, Mallinckrodt sold and distributed substantial amounts of opioids in Pennsylvania.

C. Distributor Defendants

23. At all times relevant to this controversy, the wholesale Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce opioids, without fulfilling the fundamental duty of wholesale drug distributors to

detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. This unlawful conduct by the Distributor Defendants is directly responsible for John's and the other class members' harm.

1. AmerisourceBergen

24. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is a wholesale distributor of pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

2. Cardinal Health

25. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal is a wholesale distributor of pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

3. McKesson

26. MCKESSON CORPORATION ("McKesson") is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson is a wholesale distributor of pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

III. JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over Plaintiff and the class' state law claims under 28 U.S.C. §1332(d)(1)(D)(2)(A) because the aggregated claims of the individual class members exceeds five million dollars,[10] excluding interest and costs, and there is minimal diversity of citizenship. Under 28 U.S.C. § 1332(d)(5), there are more than 100 class members.

28. This Court has personal jurisdiction over all Defendants as they have systematic and continuous contacts with this forum and have purposefully availed themselves of its benefits and protections. Specifically, the Manufacturer Defendants targeted physicians in this forum and encouraged them to prescribe opioids to citizens in this state. The Manufacturer Defendants further had actual knowledge that their opioids were being distributed and sold in this state by the wholesale Distributor Defendants and by retail pharmacies within this state. Further, direct opioid promotion efforts by the Manufacturer Defendants were specifically tailored for and directed towards this forum.[11]

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[10] In a suit seeking injunctive relief, the amount in controversy is measured by the value of the right sought to be protected by the equitable relief. *See Hunt v. Washington St. Apple Adver. Comm'n*, 432 U.S. 333, 347 (1977).

[11] *See, e.g.*, Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Pub Health. 2009 Feb; 99(2):221-7.

> Drug companies compile prescriber profiles on individual physicians—detailing the prescribing patterns of physicians nationwide—in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest … prescribers of particular drugs in a single zip code, county, [and] state[.]

29. The Distributor Defendants necessarily knew, and were legally obligated to know, that they had targeted and were selling to retail pharmacies in this state and those drugs would be dispensed to citizens of Pennsylvania.

30. Venue is appropriate in this district since Plaintiff was born here, and thus, Defendants' wrongful conduct occurred in this district and caused harm in this district.

IV. FACTS

D. Opioids and Neonatal Abstinence Syndrome

31. Opioids are a class of drugs derived in whole or part from the poppy plant. These powerful euphoria-producing and pain-reducing medications include oxycodone, hydrocodone, and morphine. While the drugs have benefits, those must be balanced against the known risk of serious harm, including addiction, overdose, death, and injury to the fetus. Women who use opioids during their pregnancy are at exceptionally high risk for giving birth to a baby who suffers from NAS. The putative class members were all diagnosed at birth with opioid-related NAS. By definition, there are no "exposure-only" or "asymptomatic" class members.

…

> A lucrative bonus system encouraged the sale representatives to increase sales of OxyContin in their territories, resulting in a large number of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them.

Upon information and belief, all Manufacturer Defendants used a same or similar promotion system which they used to target this State.

32. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012.[12] Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to 5.8 per 1000, with a total of 21,732 infants diagnosed by 2012.[13] Best estimates are that a child with NAS is born every 25 minutes.[14] According to the Pennsylvania Health Care Cost Containment Council, during a recent 12-month period, there were nearly 2,000 Pennsylvania infants born suffering from NAS, more than a 1,000% increase since 2000-2001.

33. NAS-diagnosed children "are at increased risk for neuropsychological function."[15] The challenges presented to them and their caregivers at birth are summarized as: "Do they catch up, remain at a disadvantage, or do they proceed to function even more poorly than their peers over time?"[16] Unfortunately, the new research borne about as a result of the Opioid Epidemic reveals that all children exposed to opioids and other drugs *in utero* are at a substantially higher risk for

[12] Patrick SW, et al. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012. J Perinatol. 2015 Aug; 35(8):650-5.

[13] *Id.*; Patrick SW, et al. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. 2012 May 9; 307(18):1934-40.

[14] *Id.*

[15] Nygaard E. Longitudinal cognitive development of children born to mothers with opioid and polysubstance use. Pediatr Res. 2015 Sep; 78(3):330-5.

[16] *Id.*

"lower mental abilities and more signs of attention deficits," and that these effects will persist or worsen through adolescence."[17,18]

34. Specifically, children diagnosed with NAS exhibit:

- by age 1: diminished performance on the Psychomotor Development Index,[19] growth retardation,[20] poor fine motor skills,[21] short attention span,[22] intellectual performance[23];
- between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;
- between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of

[17] *Id.*

[18] And, this is regardless of whether the child is removed from its mother or, like John Doe, remains in his mother's care. *Id.*

[19] Strauss ME, et al. Behavioral concomitants of prenatal addiction to narcotics. J. Pediatr. 1976 Nov; 89(5):842-6, and Wilson GS, et al. Follow-up of methadone-treated women and their infants: Health, development, and social implications. J. Pediatr. 1981 May; 98(5):716-22.

[20] Strauss ME, et al. Behavioral concomitants of prenatal addiction to narcotics. J. Pediatr. 1976 Nov; 89(5):842-6.

[21] Wilson GS, et al. Follow-up of methadone-treated women and their infants: Health, development, and social implications. J. Pediatr. 1981 May; 98(5):716-22, and Bunikowski R, et al. Neurodevelopmental outcome after prenatal exposure to opiates. Eur J Pediatr. 1998 Sep; 157(9):724-30.

[22] Wilson GS, et al. Follow-up of methadone-treated women and their infants: Health, development, and social implications. J. Pediatr. 1981 May; 98(5):716-22.

[23] Bunikowski R, et al. Neurodevelopmental outcome after prenatal exposure to opiates. Eur J Pediatr. 1998 Sep; 157(9):724-30.

social inhibition,[24] lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and

- after 8.5 years: significantly greater difference in cognitive scores than at previous ages, especially in girls.[25]

35. The ongoing and robust medical monitoring and treatment of opioid-related NAS-diagnosed children is medically necessary. Further, this is a rapidly transforming field, as multiple members of multiple disciplines and support systems, ranging from medical providers to psychologists to behavioral therapists to child care providers, are coming together to determine the best protocols for improving the outcomes after a diagnosis. For example, a new pilot program operated by the State of Kentucky's State Health Service Program offers a view of necessary treatment components after hospital discharge: (1) education of caregivers for techniques to relieve infant distress, including infant massage, calming techniques, and other coping skills; (2) education of caregivers about NAS and the associated symptoms; (3) frequent follow-up of the infant for growth and weight gain; (4)

[24] Oloffson M, et, al. Investigation of 89 children born by drug-dependent mothers. II. Follow-up 1-10 years after birth, Acta Paediatr Scand. 1983; 72:407-10. The researchers in this study came to the heartbreaking conclusion that "[T]here is an urgent need for health personnel to reexamine their roles in helping these children, who will otherwise develop into a new generation of social losers."

[25] Nygaard E. Longitudinal cognitive development of children born to mothers with opioid and polysubstance use. Pediatric Res. 2015 Sep; 78(3):330-5.

monthly development evaluations during infancy and toddler years to determine whether additional interventions and treatment are necessary.[26]

36. Researchers at Ohio's Case Western Reserve University School of Medicine recommend similar protocols, noting: "Intervention services for this population need to extend beyond infancy and the toddler years, since problems in cognitive, language, and behavioral functioning may persist throughout childhood."[27] In addition to the caregiver training, they recommend the following: specific individual therapy for speech and language, occupational, and behavioral; early intervention/enrichment; and ongoing cognitive and behavioral assessment.[28] Regarding the time span of necessary assessment and intervention, the researchers write: "Developmental and assessment and intervention should continue during the preschool and school years, when children may benefit from enriched educational programs and screening for special education services. Problems can compound when cognitive demands increase during the early school years. Other critical transition periods occur in the first, fourth, and sixth or seventh grades, when subtle learning and behavior problems can become more evident and lead to functional

[26] Kentucky Cabinet for Health and Family Services, Nutrition Branch, Newsletter (Fall/Winter 2016 supp.), http://chfs.ky.gov/NR/rdonlyres/FFF6F900-9982-412F-BEA5-E82542E6DF0F/0/NutritionBranch Newsletter24Supplement.pdf.

[27] Minnes S, et al. Prenatal Tobacco, Marijuana, Stimulant, and Opiate Exposure: Outcomes and Practice Implications. Addict Sci Clin Pract. 2011 Jul; 6(1):57-70.

[28] *Id.*

impairment."[29] Of equal concern is that these deficits may themselves lead to the creation of another generation of addicts. Dr. Barry Lester writes in the *Journal of Addiction Disorders*: "Prenatal drug exposure … may lead to lasting behavioral dysregulation that increases vulnerability to substances use, resulting in early onset substance use in adolescents."[30]

E. Controlled Substances and the "Closed System" of Manufacturing and Distribution

37. Prescription opioids have an extremely high potential for addiction and injury and are categorized by the United States government as "Schedule II Controlled Substances."[31] The definition of such is described by the United States Department of Justice's Drug Enforcement Agency (DEA), Diversion Control Division on its public website:

> ScheduleII/IIN Controlled Substances (2/2N)
>
> Substances in this schedule have a high potential for abuse with may lead to severe psychological or physical dependence.
>
> Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.[32]

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[29] *Id.*

[30] Lester and Legasse, "Children of Addicted Women," J Addict Dis. 2010 Apr; 29(2): 259–276. doi: 10.1080/10550881003684921.

[31] *See* Controlled Substances Act, 21 U.S.C. § 812, as supplemented by Title 21, C.F.R. § 1308.

[32] *See* https://www.deadiversion.usdoj.gov/schedules/ (visited Feb. 23, 2018).

38. Because of their known high potential for injury and addiction, these prescription drugs may only be manufactured and distributed within a "closed" system in which gatekeeper Manufacturer and Distributor Defendants are charged with the duty to prevent diversion of drugs out of the legitimate channels and into the illicit market. The Manufacturer Defendants' and the Distributor Defendants' complete and abject failure to maintain the closed system was the direct and proximate cause of the harm described in this Complaint.

39. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of registration is the "maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 USCA § 823(a)(1) (emphasis added). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act" (21 U.S.C. 823 or 958).

40. Similarly, and of equal importance, each Distributor Defendant was also required to register with the DEA, pursuant to the federal Controlled Substances Act. *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). As with the Manufacturer Defendants, federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating

substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).[33]

41. In addition to reporting all suspicious orders, Distributor Defendants must also affirmatively stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[34] Regardless, all flagged orders must be reported. *Id.*

42. Per the DEA in a letter to the Distributor Defendants in 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare

[33] These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b).

[34] *See* Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017).

of the American people."[35] Additionally, "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[36,37]

F. In Intentional and Wanton Disregard of Their Duties under the "Closed System", the Manufacturer Defendants Create Two New Markets for Prescription Opioids (and the Distributor Defendants Support Them Every Step of the Way)

43. Defendants' profits were theoretically limited by the amount of medically necessary opioids that could be sold through controlled channels. The stark reality Defendants faced was this: they could only sell so many prescription

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[35] Letter from Joseph T. Rannazzisi, Dep. Asst. Adm'r, Office of Diversion Control, Drug Enforcement Admin, U.S. Dep. of Justice to Cardinal Health (Sept. 27, 2006). ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[36] *Id.*

[37] The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007, which implored them to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explained:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. *Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.*

See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (emphasis added).

opioids to dying cancer patients. "The logic was simple: While the number of cancer patients was not likely to increase drastically from one year to the next, if a company could expand the indications for use of a particular drug, then it could boost sales exponentially without any real change in the country's health demography."[38] And, without a new and robust primary market, there would be no supply for the secondary "spill-over" diversionary market that they intended.[39]

44. Once exposed, users of the opioids could easily transition into the secondary market,[40] which was necessarily supplied from the primary market, and which Defendants were legally charged with insuring there was no supply for. Soon, the demand from the secondary market was further driving prescriptions written for the primary market.[41]

[38] Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

[39] The axiomatic nature of this relationship is recognized in Dr. Art Van Zee's examination of the OxyContin market: "The high availability of OxyContin correlated with the increased abuse, diversion, and addiction, and by 2004 OxyContin had become a leading drug of abuse in the United States." *See* "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," Am. J. Pub. Health. 2009 February; 99(2): 221-227.

[41] However, in order to maintain the highly profitable and ever-growing secondary market, the Distributor Defendants also had to conceal the true facts relating to the supply of opiates flooding the primary market. Without the silence and concealment of the Distributor Defendants, the dual market scheme (and record profits) could not have existed.

G. A New Primary Market of Prescriptions Opiates for Chronic, Widespread, Pain and Without Dose Limits

45. Thus began the Manufacturer Defendants' quest to open a new primary market for opioid prescriptions: treatment of (a) chronic, (b) widespread pain (c) without dose limits.[42] Their "ace in the hole" was this: not only could they convince physicians to write prescriptions into this new market, they could ensure through the insidious mechanism of addiction that patients, including Pennsylvania women of child-bearing age, would have to keep coming back for more.

46. With the insidious power to create both unlimited supply and unlimited demand for these highly-addictive substances, the Manufacturer Defendants set out to create the new primary market. Each of the elements of the new primary market was selected to maximize sales of the highly addictive drugs.

47. First, was the transition from a limited pool of disease and injury (cancer, disorders requiring surgery, etc.) to widespread, common diseases, such as arthritis, back pain, and joint pain. Thus, the universe of targeted patient conditions could be vastly expanded. Next was the successful promotion of highly addictive opioids for chronic, i.e., long-term conditions. Thus, step two was equally critical: ensuring that the newly targeted patient conditions would not result in one-time sales. And, finally, to ensure even further sales growth, the Manufacturer

Defendants promoted the notion that there were no dose limits and, indeed, that patients who appeared to be addicted were actually patients who should be given even more and higher dosages for opioids.[43]

48. In order to maximize profits, the Manufacturer Defendants collectively had to convince physicians to expand treatment of their patients to include chronic and "non-malignant", i.e., non-cancer, pain.[44] And, they had to do so despite the fact that the benefits of opioids are minimal, and the risks are maximal. Prospective, randomized, controlled trials lasting at least 4 weeks that evaluated the use of opioids for chronic non-cancer-related pain showed only a small to modest improvement in pain relief and no consistent improvement in physical functioning.[45] The maximal adverse risks, however, are a witches' brew and include a "high incidence of opioid abuse behaviors" and "addiction." *Id.*

[43] OxyContin was approved in 1996 for an 80mg dose. Four years later, Purdue sought and obtained FDA approval for a 160 mg dose. Mike Mariani writes: "These high-milligram pills were probably one of the biggest reasons that OxyContin became such a popular street drug.… The euphoric effects and potential for abuse were comparable to heroin." "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

[44] The science and consensus for the use of opioids in the treatment of acute pain or pain associated with cancer is "robust," due to the obvious nature of the risk/benefit analysis. Acute usage does not result in addiction. And, in cancer patients, the benefits from pain abatement greatly outweigh the known risks.

[45] Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-27 (summarizing the results of thirteen medical studies cited at fns. 24-38).

49. The market innovator that "inspired" all other Manufacturer Defendants to follow was Purdue, the maker of OxyContin. And, it was not pharmacological innovation in which it led but marketing innovation.

> Arthur Sackler [the founder of Perdue, along with his two younger brothers Mortimer and Raymond] thriv[ed] … in the fledgling field of pharmaceutical advertising. It was here that he would leave his greatest mark. As a member of … a small New York-based advertising firm, Sackler expanded the possibilities of medical advertising by promoting products in medical journals and experimenting with televisions and radio marketing. Perhaps his greatest achievement, detailed in his biography in the Medical Advertising Hall of Fame, was finding enough different uses for Valium to turn it into the first drug to hit $100 million in revenue.
>
> …
>
> Sackler was also among the first medical advertisers to foster relationships with doctors in the hopes of earning extra points for his company's drugs, according to a 2011 expose in *Fortune*. Such backscratching in the hopes of reciprocity is now the model for the whole drug marketing industry.
>
> Starting in 1996, Purdue Pharma expanded its sales department to coincide with the debut of its new drug.… Purdue increased its number of sales representatives from 318 in 1996 to 371 in 2000. By 2001, when OxyContin was hitting its stride, these sales reps received annual bonuses averaging over $70,000, with some bonuses nearing a quarter of a million dollars. In that year, Purdue Pharma spent $200 million marketing its golden goose.
>
> Boots on the ground was not the only stratagem employed by Purdue to increase sales for OxyContin. Long before the rise of big data, Purdue was compiling profiles of doctors and their prescribing habits into databases.
>
> …

> Between physician databases, incentive-happy sales reps, and an aggressive blitz package of promotional ephemera, Purdue's multifaceted marketing campaign pushed OxyContin out of the niche offices of oncologists and pain specialists and into the primary care bazaar, where prescriptions for the drug could be handed out to millions upon millions of Americans. The most scathing irony is that what allowed OxyContin to reach so many households and communities was the claim that it wasn't dangerous.

Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

H. The Secondary Market

50. As discussed at *supra*, "Controlled Substances and the 'Closed System' of Manufacturing and distribution," the Manufacturer and Distributor Defendants had an absolute and non-delegable duty to ensure that a supply of controlled substances for a secondary market did not exist. To be clear, the diversion and misuse of controlled substances is a known high-risk factor with significant negative consequences for families, communities, and even entire states. When a manufacturer or distributor who wants to deal in controlled substances registers with the DEA, they must take on a duty to prevent the known negative health effects of their addictive products.

51. In the case of prescription opiates, not only did Defendants wholly fail in that duty, but they intentionally endeavored to flood the primary market with such an excess of drugs that they either knew, or consciously and willfully disregarded the fact, that this would result in misuse and diversion into a secondary market.

Indeed, Defendants and Manufacturers flooded the United States with so many prescription opiates that our entire adult population could be dosed 6 times a day for a month.[46]

52. As will be shown, flooding an entire country with this many highly addictive opiates did not occur by accident. Instead, it occurred as the result of a highly coordinated, expensive, misleading, illegal, and callous manipulation of both the sales and distribution schemes for controlled substances within the United States.

I. The Multi-Faceted Marketing and Promotion Schemes

53. Each Manufacturer Defendant conducted, and has continued to conduct, a scheme of marketing and promotion designed to persuade doctors that opioids can and should be used for chronic pain, thereby resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. That these efforts were widely successful is evidenced by sales increases. Nationwide, from 1996 to 2002, there was a 226%, 73%, and 402% increase in fentanyl, morphine, and oxycodone prescribing respectively.[47] During that same period, misuse burgeoned.

[46] By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al. Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States. Am J Public Health. 2014 Feb; 104(2):52-9.

[47] Gilson AM, et al. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. J Pain Symptom Manage. 2004 Aug; 28(2):176-88.

Hospital emergency department admissions for fentanyl, morphine, and oxycodone increased 641%, 113%, and 346%, respectively.[48]

54. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely denied or trivialized the risks of opioids while overstating the benefits of using them for chronic pain. These false and misleading promotional claims: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal could be easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

55. The Manufacturer Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

56. The Manufacturer Defendants disseminated these common messages to reverse the previously held medical understanding of risks and benefits of opioid

[48] *Id.*

use.[49] They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

57. Purdue's efforts to promote OxyContin are illustrative of the multi-faceted promotional scheme waged by the entire industry:

> From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expense paid symposia, where they were recruited for Purdue's national speaker bureau. It is well-documented that this type of pharmaceutical company symposium influences physicians' prescribing patterns, even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.
>
> One of the cornerstones of Perdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing. Drug companies compile prescriber profiles on individual physicians—detailing the prescribing patterns of physicians nationwide—in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country. One of the critical foundations of pursue marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country.[50] The resulting database would help

[49] The "positive" physical effects of opioids are two-fold: euphoria and pain-relief. (However, medical doctors may not prescribe, nor will insurance pay, solely so that a patient may feel euphoric as that is not a medical need.) Thus, the valid medical basis for prescribing opiates is to allay pain. While temporary relief of pain is a positive, this result must absolutely be weighed against the potential for negative outcomes. In the case of opioids, the known potential negative outcome is iatrogenic addiction.

[50] OxyContin's first full year on the market was 1996. However, Purdue had an earlier history of manufacturing opiates that were abused and diverted. Its product MS Contin (morphine based)

identify physicians with large numbers of chronic-pain patients. Unfortunately, the same database would also identify which physicians were simply the most frequent prescribers of opioids and, in some cases, the least discriminate prescribers.

A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in a large number of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them.… Purdue paid $40 million in sales incentive bonuses to its sales representatives that year.

From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671 and [doubled] its total physician call list … to approximately 70,500 to 94,00 physicians. Through the sales representatives, Purdue used a patient starter coupon that provided patients with a free limited-time prescription for a 7-30 day supply.[51] By 2001, when the program was ended, approximately 34,000 had been redeemed nationally.

…

Purdue trained its sales representatives to carry the message that the risk of addiction was "less than one percent." The company cited … [two studies to support this premise]. Both of these studies, although shedding some light of the risk of addiction for acute pain, do not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. There are a number of studies, however, that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse [citing seven such studies].

From 1996 to July 2002, Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants,

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had been profitable, but by the late 1980s, its patent was running out. OxyContin was developed, in the words of its VP for Clinical Research, to "cure the vulnerability of the … generic threat [to MS Contin] and that is why it is so crucial that we devote our fullest efforts to a successful launch of OxyContin." Harriet Ryan et al., "You Want a Description of Hell? OxyContin's 12-Hour Problem," Los Angeles Times, May 5, 2016.

[51] Yes, that's right. A free coupon for 30 days' worth of a highly addictive controlled substance.

> providing a venue that had enormous influence on physicians prescribing throughout the county. Particularly, with controlled drugs, the potential for blurring marketing and education carries a much higher public health risk than with uncontrolled drugs.

Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added).

J. Two Lies: Minimizing Risks and Maximizing Benefits

1. Minimizing Risks

58. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and

are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

59. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use and each continues to fail to correct its past misrepresentations.

60. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair written representations about the purportedly low risk of addiction include:

- Purdue created literature and audiotapes for physicians and a "Partners Against Pain" Website in which it claimed over and over that the risk of addiction from OxyContin was extremely small.[52]

- Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem."

[52] Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added), *citing* Irick, N. *Overcoming Barriers to Effective Pain Management* [audiotape]. Rochester, NY: Solutions Unlimited; March 2000; Carr, B., *The Impact of Chronic Pain—An Interdisciplinary Perspective*, Continuing Medical Education program. New York, NY: Power-Pak Communications; 2000; 925 Program 424-000-99-010-H01; Lipmann, A., *Use of Opioids in Chronic Noncancer Pain*. Continuing Medical Education program. New York, NY: Power-Pak Communications; April 2000:6; *Pain Management* [CD and slide instructional program for physicians]. Stamford, CT: Purdue Pharma; 2002; *Dispelling the Myths about Opioids* [brochure for physicians]. Stamford, CT: Purdue Pharma; 2002.

Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

- Cephalon and Purdue sponsored the American Pain Foundation's "Treatment Options: A Guide for People Living with Pain" (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[53]

- Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you Know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

- Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled "Living with Someone with Chronic Pain," which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

- Janssen reviewed, edited, approved, and distributed a patient education guide entitled "Finding Relief: Pain Management for Older Adults" (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

[53] Am. Pain Found., Treatment Options: A Guide for People Living in Pain (2007) [hereinafter "APF Treatment Options"], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

- Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

- Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[54]

61. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, sales representatives for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above. Of these efforts, Dr. Van Zee writes: "Purdue trained its sales representatives to carry the message that the risk of addiction 'was less than one percent.'"

62. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[55] The 2016 CDC Guideline further explains that "[o]pioid pain

[54] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter "APF, Policymaker's Guide"], http://s3.documentcloud.org/ documents/277603/apf-policymakers-guide.pdf.

[55] Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United

medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[56]

63. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[57]

States, 2016, Morbidity & Mortality WNly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[56] *Id.* at 2, 25.

[57] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer? documentId=FDA-2012-P-08180793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

64. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[58] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.

65. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e., pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

[58] Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo AOD 030116-Fully Executed.pdf.

66. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." A paid industry "Key Opinion Leader" (KOL)[59] Dr. Russell Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.[60] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[61]

- Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated.… Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

- Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

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[59] As physicians must choose from a myriad of drug options to treat their patients, they often rely on fellow physicians perceived as having superior knowledge in the area. These "Key Opinion Leaders" are ferreted out through a data-driven profiling system, and then targeted by pharmaceutical companies to promote certain drugs. The KOLs can both help spread information about the drug and expand markets. Indeed, the cultivation and management of KOLs is seen by the pharmaceutical industry wholly as a "business function."

[60] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

[61] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

- Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

- Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

67. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

68. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lacked the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer

Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Examples include:

- Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

- Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

- As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

69. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[62]

[62] *Id.* at 11.

70. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example:

- Upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

- Purdue sponsored APF's A *Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[63]

71. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment

[63] APF, *Policymaker's Guide, supra* note 48, at 32.

when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

- Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

- Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[64] This publication is still available online.

- Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

- Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics (2004 Endo Pharmaceuticals PM- 0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased … You won't 'run out' of pain relief."[65]

- Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

[64] *Id.*, note 47, at 12.

[65] Margo McCaffery & Chris Pasero, Endo Pharm., Understanding Your Pain: Taking Oral Opioid Analgesics (Russell K Portenoy, M.D., ed., 2004).

- Upon information and belief, Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

- Purdue sponsored APF's "A Policymaker's Guide to Understanding Pain & Its Management," which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[66]

- In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

- Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[67]

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[68]

72. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence.

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[66] APF, *Policymaker's Guide, supra* note 48, at 32.

[67] The College on Problems of Drug Dependence, About the College, http://cpdd.org (last visited Aug. 21, 2017).

[68] Brief of APF, *supra* note 49, at 9.

The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[69] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[70] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression[71], and death at higher dosages."[72] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[73]

73. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush-resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013

[69] 2016 CDC Guideline, *supra* note 46, at 22–23.

[70] *Id.* at 23-24.

[71] Indeed, Purdue Pharma had withdrawn its hydromorphone-based opiate "Palladone" after only six months on the market in 2005, because patients kept dying when they stopped breathing or else went into comas.

[72] 2016 CDC Guideline, *supra* note 46, at 21.

[73] *Id.* at 16.

letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[74] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[75] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[76] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

2. Maximizing the Benefits, Especially as Compared to other Non-Addictive Alternatives

74. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other

[74] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin. U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[75] *Id.* at 6.

[76] *Id.* at 6, n.21

treatments were more or equally beneficial and less harmful than long- term opioid use.[77] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

75. Examples of the Manufacturer Defendants' false claims are:

- Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

- Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

- Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

- Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

- Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions

[77] *Id.* at 15.

persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

- Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

- Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[78] This publication is still available online.

- Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[79] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

- Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the

[78] APF, Treatment Options, supra note 47. 66 E.g., NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

[79] *E.g.*, NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/ Activities/B173_Providence_RI_%20Invite.pdf.

"Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

- Purdue sponsored the development and distribution of APF's "A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[80] The Policymaker's Guide was originally published in 2011.

- Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

76. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[81] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall

[80] APF, *Policymaker's Guide, supra* note 48, at 29.

[81] Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

77. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[82]

78. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately

[82] 2016 CDC Guideline, *supra* note 50, at 12.

40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

79. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

80. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills

> can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[83]

81. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[84] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are opioid-tolerant,

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[83] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, Howland v. Purdue Pharma L.P., No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

[84] *See* U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarNetDrugSafetyInformationforPatientsandProviders/ucm05 1273.htm.

meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[85]

82. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

- Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

- In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special

[85] *Id.*

> Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

83. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

84. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even when Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers: despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring"

until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[86]

85. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

K. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations

86. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors who were more likely to treat chronic pain patients and prescribe them drugs but were less likely to be

[86] Harriet Ryan et al., More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me- oxycontin-part2/.

educated about treating pain and the risks and benefits of opioids and, therefore, more likely to accept the Manufacturer Defendants' misrepresentations.

87. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[87] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post- traumatic stress disorder, which interact dangerously with opioids.

L. The Manufacturer Defendants made False Statements and Concealed Material Facts

88. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription

[87] 2016 CDC Guideline, *supra* note 50, at 13.

opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

1. Purdue

89. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

2. Endo

90. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Funding and directing pro-opioid pain organizations (including over $5 million to the organization responsible for many of the most egregious misrepresentations) that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

3. Janssen

91. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

4. Cephalon

92. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

5. Actavis

93. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

M. Each Manufacturer Defendant Used Multiple Avenues to Disseminate False Statements about Opioids

94. The Manufacturer Defendants spread their misinformation detailed above by multiple channels, including by deployed seemingly unbiased and independent third parties that they controlled, including recruited speakers. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

95. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

1. Direct Marketing

96. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

97. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction

worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

98. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

99. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by

individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

100. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize ... the risks associated with Kadian and misleadingly suggest … that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, [and] use by individuals other than the patient for whom the drug was prescribed."[88]

2. Indirect Marketing

101. The Manufacturer Defendants' indirectly and collusively marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

102. The Manufacturer Defendants deceptively marketed opioids throughout the United States through unbranded advertising – i.e., advertising that

[88] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/ resources/files/archives/a/ActavisElizabethLLC.pdf.

promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third parties.

103. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

104. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have

long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

105. In 2007, multiple states sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promoting prescribing practices which have worsened the opioid crisis.

106. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's

failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

107. Defendants utilized many KOLs, including many of the same ones. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

108. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched

program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[89]

109. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[90] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[91]

110. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unremarkable pain clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013. He is

[89] Good Morning America (ABC television broadcast Aug. 30, 2010).

[90] Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[91] *Id.*

a Senior Editor of "Pain Medicine", the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

111. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

112. Ironically, Dr. Webster created and promoted the "Opioid Risk Tool," a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's "Opioid Risk Tool" appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the "Opioid Risk Tool" into their own guidelines,

indicating also their reliance on the Manufacturer Defendants and those under their influence and control.

113. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors throughout the United States.[92]

114. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book "Avoiding Opioid Abuse While Managing Pain"—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[93] Upon information and belief, Endo distributed this book to doctors.

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[92] *See* "Emerging Solutions in Pain, Managing Patient's Opioid Use: Balancing the Need and the Risk," http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued& view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017.

[93] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[94]

115. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

116. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted

[94] John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn- 139609053.html.

to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

117. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including APS, American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF"), and the Pain & Policy Studies Group ("PPSG").[95]

118. The most prominent of the Manufacturer Defendants' Front Groups was APF which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high

[95] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

rates of addiction and other adverse outcomes– including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of all 50 states.

119. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

120. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant

was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

121. Plaintiff is informed, and believes, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

122. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[96]

[96] Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel- investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

123. Another front group for the Manufacturer Defendants was AAPM. With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

124. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at offsite dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

125. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on

opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

126. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

127. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patient becoming addicted to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[97]

128. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[98] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants.

[97] The use of opioids for the treatment of chronic pain. A consensus statement from the American Academy of Pain Medicine and the American Pain Society. Clin J Pain. 1997 Mar; 13(1):6-8.

[98] Chou R, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain. 2009 Feb; 10(2):113-30.

Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

129. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[99]

130. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature,

[99] *Id.*

were disseminated in the State and/or Plaintiff's Communities during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

131. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

N. The Manufacturer Defendants Misrepresented Their Misconduct

132. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their

misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience, establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

133. At all times relevant to this Complaint, the Manufacturer Defendants took steps to conceal and misrepresent their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and

benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

134. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a

period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

O. Defendants' Abject Failure to Maintain the Closed System of Manufacturing and Distribution

135. Concurrent with their promotional and marketing campaign, the Manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their shared legal duty both to investigate and notify authorities of all suspected diversions of these highly dangerous substances.

136. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The

Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

137. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

138. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[100]

139. In the press release accompanying the settlement, the Department of Justice stated:

> Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone… Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street.… Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.][101]

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[100] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement- failure-report-suspicious- orders.

[101] *Id.*

140. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[102]

141. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[103]

142. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> - conduct adequate due diligence of its customers;

[102] *Id.*

[103] *Id.*

- detect and report to the DEA orders of unusual size and frequency;

- detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007;

- orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion;

- orders that purchased a disproportionate amount of substance which is most often abused compared to other products; and

- orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware; iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[104]

143. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they

[104] 2017 Mallinckrodt MOA at 2-3.

manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[105]

144. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[106]

145. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

146. The same business practices utilized by Mallinckrodt regarding "chargebacks" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Distributor

[105] *Id.* at 3-4.

[106] *Id.* at 5.

Defendants. Through, *inter alia*, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful. The Manufacturer Defendants have misrepresented their compliance with federal law.

147. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's claims below.

148. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled, caused, and contributed to the unlawful diversion of opioids throughout the United States.

V. CLASS ACTION ALLEGATIONS

P. Certification under FED. R. CIV. P. 23(b)(2)

149. This action is brought under Federal Rule of Civil Procedure 23(b)(2) in that Defendants both acted and refused to act on grounds that that apply generally to the class, so that final injunctive relief is appropriate respecting the class as a whole. Plaintiff, through his guardian and next friend, brings this action on his own

behalf, and on behalf of all others similarly situated, as representatives of the following class:

> Pennsylvania residents born after August 24, 1998, who were medically diagnosed with opioid-related NAS (also sometimes referred to as Neonatal Opioid Withdrawal Syndrome (NOWS)) at or near birth and whose birth mother received a prescription for opioids or opiates manufactured or distributed by a Defendant prior to the birth of that child. Excluded from the class are any infants and children who were exposed to opioids only after birth, for a purpose other than pharmacological weaning.[107]

150. The members of the class are readily identifiable from medical records and pharmacy records.

151. As set forth above, Defendants have acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

[107] There are only two causes of NAS: (1) *in utero* exposure to opioids *via* the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

152. As discussed herein, all children diagnosed with NAS[108] must receive robust medical testing, monitoring, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for these symptomatic children. Because the treatment goal of the requested robust medical monitoring plan is to maximize the developmental outcomes of each of these children, it is irrelevant that they might begin at different developmental levels due to the severity of exposure or ultimately end up at different developmental levels. The Court should enter an injunction requiring Defendants to provide this relief to Plaintiff and to the class.

153. Upon information and belief, the class consists of thousands of members and is so numerous that individual joinder of all members is impracticable. The members of the class are geographically dispersed throughout Pennsylvania.

154. There are questions of law and fact common to the class, which predominate over any questions affecting only individual members of the class. The wrongs suffered and remedies sought by Plaintiff and the other members of the class are premised upon a uniform unlawful scheme perpetuated by Defendants. The sole question affecting only individual members of the class is the exact monetary recovery for past medical expenses to which each class member is entitled, which

[108] Because the class members received a medical diagnosis of NAS at or near birth, there is no question of whether they received a "dosage" or "exposure" adequate enough to warrant medical monitoring.

monetary recovery is incidental to the injunctive relief of medical monitoring and treatment sought. The use of uniform billing codes for patients with opioid conditions will render this determination a simple mechanical one.

155. Questions common to the class include, but are not limited to, the following:

- Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and/or report suspicious orders of prescription opioids?

- Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and/or report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids for treatment of chronic pain?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids for treatment of non-cancer pain, including but not limited to widespread conditions such as arthritis and joint pain?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids as drugs without dose limits?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids by misrepresenting both their risks and their benefits?

- Did the Manufacturer Defendants negligently manufacture, market, promote, and sell opioids?

- Did the Distributor Defendants negligently sell and distribute opioids?

- Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, promote, and sell opioids?

- Did the Distributor Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?

- Were Plaintiff and the class members damaged as a direct and proximate result of the Defendants' acts and omissions?

156. Plaintiff's claims are typical of those of the class and are based on the same legal theories as those of the class members. Plaintiff's claims and those of the class members all arise from the same pattern or practice by Defendants, set out above.

157. Plaintiff, by and through his guardian and next friend, will fairly and adequately protect the interests of the members of the class. Plaintiff has retained counsel who are highly experienced and competent in class-action litigation, and Plaintiff and his counsel intend to prosecute this action vigorously. Neither Plaintiff nor his counsel have any interests that might cause them not to vigorously pursue this action. Plaintiff's interests are coextensive with those of the class, and Plaintiff has no interests adverse to those of the class members.

158. Plaintiff has made arrangements with his counsel for the discharge of his financial responsibilities to the class. Plaintiff's counsel has the necessary financial resources to adequately and vigorously litigate this class action.

Q. Alternative Certification under FED. R. CIV. P. 23(b)(3)

159. Alternatively, and only if the Court finds that this is not an appropriate action for FED. R. CIV. P. 23(b)(2) certification, Plaintiff requests alternative certification under 23(b)(3).

160. Common questions of law predominate. Furthermore, a class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual class members may be unaware of their rights. Thus, it is unlikely that the class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

R. Alternative Certification under FED. R. CIV. P. 23(b)(1)

161. Prosecuting separate actions by individual class members would create a risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for Defendants.

S. Interim Appointment of Class Counsel under FED. R. CIV. P. 23(g)(2)

162. Interim appointment of class counsel to represent the putative class in prosecuting this action is warranted and is necessary to defend against expected motions to dismiss and to manage precertification matters on behalf of the putative class.

VI. CAUSES OF ACTION

T. First Cause of Action — Public Nuisance

163. Plaintiff incorporates by reference each of the preceding paragraphs as though fully set forth herein.

164. The opioid epidemic in Pennsylvania and the resulting public health and safety crisis constitute a public nuisance. The use of prescription opioids for medical purposes beginning in at least the mid-1990s and continuing to the present has led to a sharp increase in the incidence and prevalence of NAS. Neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of a child's adolescent development and result in significant adverse societal impacts to public health, safety and peace of Plaintiff and the class. The

NAS-diagnosed cohort of Pennsylvanians are themselves damaged, and also Pennsylvanians as a whole, causing deterioration in public order, public safety, economic productivity, and the quality of life for Plaintiff, the class, and their fellow Pennsylvanians. The epidemic of NAS-diagnosed children has shifted the imposition of the social costs of the opioid epidemic to Plaintiff, the class, and their fellow citizens from those responsible.

165. Defendants herein have engaged in systematic deceptive marketing and promotion of prescription opioids for medical uses for several decades. This misconduct, as set forth above, has created, caused and/or substantially contributed to the public nuisance.

166. Defendants' misconduct as set forth above has created or contributed to a substantial and unreasonable interference with rights common to the general public, including the right to be free of an unreasonable interference with public health, safety and peace.

167. Defendants' interference with the public health, safety and peace of Plaintiff and the class through their misconduct has been unreasonable, as established by the following circumstances as more fully alleged previously herein:

a. Defendants' misconduct is responsible for the epidemic of NAS-diagnosed children in Pennsylvania and significantly interfered with public health, safety and peace of Plaintiff, the class, and their fellow citizens;

b. Defendants' misconduct has produced a permanent or long-lasting effect and will continue unless the prescription and use of opioids as a treatment for chronic pain and as marketed and sold by Defendants are reduced to appropriate levels, and unless Plaintiff and the class suffering from NAS receive adequate medical monitoring and treatment;

c. Defendants knew or had reason to know that their misconduct has had and continues to have a significant adverse impact on public health, safety and peace; and

d. Defendants' interference with rights common to the public, including Plaintiff and the class, is and was unreasonable based on the totality of the circumstances.

168. The unreasonableness of Defendants' conduct and the resulting substantial harm imposed on Plaintiff and the class, and the infringement of their rights, is evident from the gravity of the harm and from the accompanying serious effects of NAS-diagnosed children that interfered with and degraded, and continues to interfere with and degrade, the public health and safety of Plaintiff and the class.

169. The epidemic of NAS-diagnosed children and resulting public health and safety crisis touch and harm many neighborhoods, workplaces and communities in Pennsylvania. The harm is not confined to any City zip code or census tract, or to people of any race, ethnicity, religion, gender, sexual preference, or other

demographic, but affects the public health, safety, order and well-being of the citizens as a whole, including Plaintiff and the class.

170. The deterioration of public health and safety caused by the epidemic of NAS-diagnosed children tears at the social and economic fabric of Pennsylvania. The affected children will be students in Pennsylvania schools and users of its medical care, and members of the workforce. The societal costs of their condition will be socialized and ultimately borne by the State as a whole, including Plaintiff and the class. The negative effects of the opioid crisis on the public health, safety and peace of Plaintiff and the class are substantial and statewide.

171. The following additional circumstances also further support Plaintiff's public nuisance claim:

a. Defendants had sufficient control over, and responsibility for, the public nuisance they created, as alleged more fully herein. Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of marketing and promotion and creation and maintenance of the demand for prescription opioids at all relevant times, which included control of the misleading representations they conveyed through branded and unbranded marketing and product promotion. Defendants could have ameliorated, at least in part, the public nuisance by ceasing their improper marketing of opioids and their dissemination of

misleading messages about the safety and efficacy of opioids, and by disseminating corrective statements that informed physicians, consumers, third-party payors and health plan administrators and others about the true risks of prescription opioids.

b. Defendants are not immune from public nuisance claims because they produced and marketed otherwise and/or allegedly legal products. Lawful conduct of businesses, like lawful conduct of individuals, has long been held to constitute a public nuisance if it unreasonably interferes with public health, safety, or peace. In any event, Defendants' conduct – and the deceptive marketing and product promotion and misrepresentations and omissions embodied therein – was unlawful.

c. Defendants have interfered with common public rights, which were understood for centuries to be and have become common rights to public health, safety, order, peace, comfort, or convenience, rather than specific, individual rights.

172. Defendants' misconduct has not been insubstantial nor fleeting as it has involved sophisticated and highly wrongful conduct involving expenditures of tens of millions of dollars per year by Defendants to market and promote prescription opioids and which they engaged in for decades. The misconduct is ongoing and has produced permanent or long-lasting harm, including the worst drug epidemic in the

history of the country, along with all of the deleterious consequences thereof as more fully alleged herein, including the births of NAS-diagnosed children. Defendants' misconduct has caused significant disruption of the public health, safety and peace of Plaintiff and the class, as further alleged herein.

173. The injury, damage and costs to Plaintiff and the class from Defendants' misconduct were both significant and either known or wholly foreseeable to Defendants. While reaping billions of dollars in revenues and profits through their misconduct, Defendants improperly shifted the burden, harm and costs of their public nuisance to Pennsylvanians, including Plaintiff and the class, as alleged herein.

174. The public nuisance for which Defendants are responsible has caused, and continues to cause, substantial, extraordinary and repeated injury to Plaintiff and the class that will continue unless enjoined and remedied by the Court.

175. Plaintiff and the class have been injured and continue to be injured in that, among other things, they have been forced to pay for a variety of social, public health, emergency, medical, and other services, the need for which arose from the opioid epidemic, as alleged above. Plaintiff and the class have also been directly injured in that they have related medical treatment due to prescription opioids marketed by Defendants, as alleged more fully herein.

176. Plaintiff and the class sue for all appropriate injunctive and mandatory relief to abate the ongoing public nuisance, restore their public health, safety and peace, and recover all appropriate damages, expenses, costs, and fees.

177. Plaintiff and the class sue for all appropriate injunctive and mandatory relief to abate the ongoing public nuisance, restore their public health, safety and peace, and recover all appropriate damages, expenses, costs, and fees.

178. Defendants also are liable for punitive damages to reflect the aggravating circumstances of their intentional, willful, wanton, malicious, and oppressive conduct, as set forth herein. Defendants acted or failed to act knowingly, willfully and deceptively, with gross negligence, maliciously, and/or wantonly with conscious disregard of the public health, safety, and welfare of Plaintiff and the class.

U. Second Cause of Action — Negligence

179. Plaintiff hereby incorporates by reference each of the preceding paragraphs as though fully set forth herein.

180. Defendants owed a duty to Plaintiff and the class to disclose the true nature of the opiates they manufactured, marketed, and distributed. They also had a duty to disclose the adverse consequences of these drugs, while at the same time correctly stating the known benefits. In addition, Defendants had a duty to prevent the diversion of these drugs. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the

opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of registration is the "maintenance of *effective controls against diversion* of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 USCA § 823(a)(1) (emphasis added). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act" (21 U.S.C. 823 or 958).

181. Similarly, and of equal importance, each Distributor Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II

controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). As with the Manufacturer Defendants, federal regulations impose a *non-delegable duty* upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).[109]

182. In addition to reporting all suspicious orders, Distributor Defendants must also affirmatively stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after

[109] These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b).

conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[110] Regardless, all flagged orders must be reported. *Id.*

183. Defendants' breach of each of the aforementioned duties resulted in a foreseeable harm to Plaintiff.

V. Third Cause of Action — Negligence *Per Se*

184. Plaintiff hereby incorporates by reference each of the preceding paragraphs as though fully set forth herein.

185. Defendants owed non-delegable statutory duties to Plaintiff and the class. These duties were established to prevent the specific type of harm of which Plaintiff suffered. Defendants had a duty to prevent the diversion of the drugs which harmed Plaintiff and the class members. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of registration is the "maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of

[110] *See* Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017).

such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 USCA § 823(a)(1) (emphasis added). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act" (21 U.S.C. 823 or 958).

186. Similarly, and of equal importance, each Distributor Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). As with the Manufacturer Defendants,

federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).[111]

187. In addition to reporting all suspicious orders, Distributor Defendants must also affirmatively stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[112] Regardless, all flagged orders must be reported.

188. The harm caused to Plaintiff and the class members were a foreseeable result of Defendants' breach of their statutory duties.

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[111] These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b).

[112] *See* Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017).

W. Fourth Cause of Action — Medical Monitoring

189. Plaintiff hereby incorporates by reference each of the preceding paragraphs as though fully set forth herein.

190. Plaintiff and the class, who were all diagnosed with NAS, were exposed to opiates above background levels. Opiates are a known hazardous substance dangerous to human health if administered improperly and are especially contraindicated for women of child-bearing age and pregnant mothers.

191. Plaintiff and the class were exposed to the opiates as a result of Defendants' negligence. As a result of the exposure, Plaintiff and the class have an increased risk of additional latent disease and other effects, including future learning impairment and other deficits.

192. A monitoring program procedure exists that makes the early detection and treatment of disease possible. Defendants should be ordered to provide a monitoring program reasonably necessary according to contemporary scientific principles to Plaintiff and the class. Plaintiff and the class members require follow-up testing, monitoring, training for their caregivers (who include grandparents, foster parents, biological parents, adoptive parents, and legal guardians) and referrals for medical, psychological, and behavioral treatment. Ultimately, the goal is maximizing the development of each exposed child.

VII. RELIEF REQUESTED

WHEREFORE, Plaintiff, by and through his guardian and next friend, and the putative class respectfully request any and all injunctive relief to which Plaintiff and the class show themselves to be justly entitled, including but limited to:

A. Ordering Defendants to provide ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for symptomatic children who have been diagnosed with opioid-related NAS, and all future medical care reasonably necessary to treat these children.

B. Ordering injunctive relief and abatement of the public nuisance committed by Defendants, to the fullest extent allowed by law, including an abatement fund.

C. Awarding all incidental damages and medical expenses incurred by Plaintiff and the class in connection with their treatment for NAS. It is expressly alleged that all medical expenses being sought are incidental to the injunctive relief requested by Plaintiff and the class.

D. Awarding punitive damages.

E. Awarding attorneys' fees and costs incurred by Plaintiff and the class.

F. Awarding all other relief, at law or in equity, to Plaintiff and the class which may be just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Respectfully submitted,

s/ John K. Weston

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